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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/595,526	06/16/2000	Richard M. Lawn	99.395-A	9969

7590

09/18/2002

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EXAMINER

RAO, MANJUNATH N

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 09/18/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/595,526

Applicant(s)

LAWN ET AL.

Examiner

Manjunath N Rao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,25-32 and 35-76 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5-7,10,13,16,20 and 23 is/are allowed.
- 6) ☒ Claim(s) 33 is/are rejected.
- 7) ☒ Claim(s) 3,4,8,9,11,12,14,15,17-19,21,22 and 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 June 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5,8
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Claims 1-76 are presently pending in this application. Claims 3-24 and 33-34 are now under consideration. Claims 1-2, 25-32, 35-76 remain withdrawn from consideration as being drawn to non-elected invention.

Election/Restrictions

Applicant's election of Group II, claims 3-24, 33-34 in Paper No. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Drawings

The drawings submitted in this application are accepted by the Examiner for examination purposes only.

Sequence Compliance

Applicant is required to comply with the sequence rules by inserting the sequence identification numbers of all sequences recited within the claims and/or specification. It is

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particularly noted that figure 13, and sequences recited on pages 32 and 75 do not refer to any specific SEQ ID NO. See particularly 37 CFR 1.821(d).

Claim Objections

Claim 3 is objected to because of the following informalities: Claim 3 depends from claims 1 and 2 which are non-elected claims. Appropriate correction is required.

Claims 3, 34 and claims 4, 8-9, 11-12, 14-15, 17-19, 19, 21-22, which depend from claim 3 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential step, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step is: Culturing of the recombinant host cell comprising the vector expressing ABC1 protein before the purification step.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claim 18 is rejected because, the invention appears to employ novel vector. Since the vector is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed plasmids' sequences are not fully disclosed, nor have all the sequences required for their construction been shown to be publicly known and freely available. The enablement requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the plasmids. The specification does not disclose a repeatable process to obtain the vector and it is not apparent if the DNA sequences are readily available to the public. Accordingly, it is deemed that a deposit of this plasmid should have been made in accordance with 37 CFR 1.801-1.809.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Becq et al. (JBC, 1997, Vol. 272(5):2695-99) and the high level of knowledge in the art of molecular biology. Claim 33 in this instant application is drawn to a method of producing an ABC1 protein in a mammalian host cell comprising transfecting the mammalian host cell with a recombinant expression vector encoding ABC1 followed by culturing the host cell and purifying the protein produced.

Becq et al. teach the *in vitro* production of ABC1 protein. However, the method uses cRNA which is injected into frog oocytes and the encoded protein is assayed as opposed to the above

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claim wherein the host is a mammalian cell. With the reference of Becq et al. in hand, it would have been obvious to one of ordinary skill in the art to make a cDNA using the mRNA of ABC1 protein used in the above reference and subclone such a cDNA into a expression vector and transfect a mammalian cell such that the mammalian produced the protein when cultured. One of ordinary skill in the art would have been motivated to do so as the method of Becq is limited to use of oocytes and is quite cumbersome. One of ordinary skill in the art would have a reasonable expectation of success since Becq et al. provide the cRNA or the mRNA encoding the protein and the it is common knowledge in the art to convert the mRNA or cRNA sequence information into a cDNA and subclone it into a expression vector than can be expressed in a mammalian cell.

Therefore the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art.

Allowable Subject Matter

Claims 5-7, 10, 13, 16, 20 and 23 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 6:30 a.m. to 3:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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A handwritten signature in black ink, appearing to read "Manjunath N. Rao". The signature is fluid and cursive, with a large initial "M" and a stylized "R".

Manjunath N. Rao Ph.D.
Patent Examiner, A.U. 1652
9/17/02